

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2104000	(X3) Date Survey Completed 11/16/2021
Name of Provider or Supplier Dermisurgery Associates Kingwood Lab	Street Address, City, State 19701 Kingwood Drive Bldg 6, Kingwood, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of patient slides from 2020 and 2021, and staff interview, it was revealed that the laboratory failed to follow its policy for labeling slides for eight of 20 patient's slides reviewed for 2020 and 2021. Findings include: 1. A review of the laboratory's policy titled 'Labeling of Frozen Section Slides' revealed the following: "Slides are to be labeled before frozen sections are cut: - Line 1 - Surgery Accession (Case) number - Line 2 - Patient name: Last name, First initial" 2. A random review of patient slides from 2020 and 2021 revealed the following 8 patient slides were not labeled as required per the</p>

laboratory's policy: 21KD-269 - slide did not include the patient's first initial 21KD-259 - slide did not include the patient's first initial 21KD-197 - slide did not include the patient's first initial 21KD-169 - slide did not include the patient's last name and first initial *this slide also included a second case number of 21KD-089 20KD-188 - slide did not include the patient's last name 20KD231 - slide did not include the patient's last name 20KD-186 - slide did not include the patient's last name and first initial 20KD-027 - slide did not include the patient's first initial 3. An interview with the operations director on 11/16/19 at 2:20 p.m. in the laboratory, after review of the records, confirmed the above findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observation of supplies available for use in the laboratory and staff interview, it was revealed that the laboratory failed to ensure one of two bottles of StatLab Gill 3 Hematoxylin stain was not to be used when it exceeded its expiration date. Findings include: 1. Surveyor observation of supplies available for use in the laboratory on 11/16/21 at 2:10 p.m. identified the following expired stain: a) StatLab Gill 3 Hematoxylin stain Lot # 091751 expiration: 6/30/21 2. An interview with the operations director on 11/16/21 at 2:10 p.m. in the laboratory confirmed the supplies were available for use and expired. This confirmed the above findings.